ITS Intertek Testing Services
ETL SEMKO

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Dockets Management Branch (HFA-305)
Center for Devices and Radiological Health
United States Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

August 28, 2000

RE: FDA Docket No. 98N-0331 (CDRH Draft Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997)

Dear Sir or Madam,

Intertek Testing Services welcomes the FDA initiative to broaden the number of devices eligible for 510(k) review by third parties. Intertek testing Services, ETL SEMKO division echoes the Agency's disappointment in the lack of utilization of Third Parties. However we believe that an effective expansion of the program and the efforts of the medical industry trade associations and the Agency will address this problem.

We have some comments however regarding the Draft Guidance document where we consider some clarification and/or amendment is necessary. These are outlined in this document:

1. Device that is the 'same or similar medical specialty

"Reviews of a device under the new list must be a device that is the 'same or similar medical specialty area as the device the Accredited Person now intends to review.' "

In our opinion, due to the type and nature of the products which third parties have been able to review to date, the proposed limitations restrict the benefit of the proposed extension of the program. The medical industry is aware of the draft extension of the devices available for 3rd party review and certain expectations will follow. However, we consider the necessity for demonstrating that the product is the same or similar to a device already examined will negate any benefit of the proposed extension. When an Accredited Person has shown competence in the areas approved for review, and has attended a course similar to those performed under the Pilot program in 1996 and again for third parties in 1998, then this should be sufficient. Where no device-specific review guidance documents exist, pre-review discussions with ODE will act as a "safety valve".

When applying the new requirements however, we consider that the Accredited Person could be denied the ability to conduct a product review in a medical specialty area where the Accredited Person has been previously accredited by FDA. This could restrict the number of product types rather than expand them.

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2. Pre-review discussion with ODE

The June 12 draft requires that:

1) *The Accredited Person has previously completed three successful 510(k) reviews under the third party program. This should include at least one 510(k) review that was in the same or similar medical specialty area as the device the Accredited Person now intends to review. The prior 510(k) reviews can be for Class II devices that have device-specific guidance or for Class I devices;*

2) *The Accredited Person contacts the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) before initiating a 510(k) review for a Class II device that does not have a device-specific guidance to confirm that the Accredited Person meets the criteria in paragraph 1 above for review and to identify pertinent issues and review criteria related to this type of device; and*

3) *The Accredited Person prepares a summary documenting the discussions and submits the summary of those discussions to ODE.*

We have a concern that in accordance with what is written (implicit rather than explicit) the ODE could withhold permission, for an indefinite period, for the third party to conduct a review. There is no reference to a procedure or to a commitment to resolve issues in an expedient manner.

We have a concern that the availability of information and the turnaround times with ODE could become "self limiting". The success of the program relies on information exchange. We need access to the type of information that a FDA internal reviewer has access to. For example it is probable that ODE uses some or all of the following routinely:

- Checklists
- Copies of decisions by product type
- Copies of controls necessary by product type (e.g. what clinical data is considered adequate)

We are concerned that communication times between ODE and Third Parties could lengthen reviews to the point where it becomes non-viable for the Third Party to attempt a review for devices where ODE has to be involved. This would defeat the intent of the proposed extension of the devices available for review.

We suggest that a "knowledge base" (available to all Third Parties) be created to allow all Third Parties to have access to the knowledge and experience gained during the "Pilot Period". The "knowledge base would contain sufficient information to allow confidence to build between Third Parties and ODE and reduce discussions about devices where the requirements for review are documented and clarified. To help build the level of confidence between ODE and Third Parties, a regular venue could be established where matters of interpretation, training, and experiences could be aired for the benefit of all concerned.

3. Conflict of Interest

Pages 14 and 15 of the Draft Guidance document states:

"If FDA monitoring of the program reveals that manufacturers are developing business relationships with Accredited Persons that call into question the independence or objectivity of the Accredited Person, FDA will consider implementing a process that limits the submitter's choice of Accredited Persons for a specific review."

Business relationships in the conformity assessment industry are built on trust. At present it would be impossible for a Third Party to exist solely on the revenues generated from 510(k) reviews. The business relationship builds confidence and experience between the Third Party and the manufacturer.

With the proposed expansion, and especially for reviews where the ODE must be consulted, there will be a joint learning experience where manufacturers have to rely on the Third Party even more than before. This naturally creates a closer relationship between the two parties. It does not naturally lead to a loss of objectivity or impartiality.

"Business relationships that may undermine the independence or objectivity of an Accredited Person include contracts between a manufacturer and an Accredited Person that represent a significant share of the Accredited Person's income over the period of the contract, such that continuation or termination of the contract may create the appearance of an undue financial influence."

Our concern is that FDA may act upon the number of 510(k) documents issued for a single client rather than establish if objectivity has been lost or that the Third Party relies on the income from the manufacturer as a substantial proportion of the Third Party's income.

We would be pleased to be part of a discussion group formed to discuss these comments and those from other third parties that have responded.

Sincerely,

Donald J Sherratt
Medical Stream Director

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